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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,331	07/25/2003	Arthur M. Krieg	C1039.70078US00	4362

7590 10/12/2006

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EXAMINER
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LE, EMILY M

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/627,331

Applicant(s)

KRIEG ET AL.

Examiner

Emily Le

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 7/25/03+11/22/04.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 50, 52, 53, 55-57, 59, 60, 62-64, 66-70 and 72-96 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 50, 52-53, 55-57, 59-60, 62-64, 66-70 and 72-96 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-49, 51, 54, 58, 61, 65 and 71 are cancelled. Claims 50, 52-53, 55-57, 59-60, 62-64, 66-70 and 72-96 are added via preliminary amendments filed 7/25/2003 and 11/22/2004. Claims 50, 52-53, 55-57, 59-60, 62-64, 66-70 and 72-96 are pending.

### ***Election/Restrictions***

2. The following restriction requirement replaces the previously issued restriction requirement. Previously, the Office inadvertently gathered that all claims are unified to hepatitis B viral infection. However, it is now noted that claims directed to both hepatitis B and C are present in the claims. Hence, a new restriction requirement is necessary.

The Office regrets any inconvenience this may cause Applicant.

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 50, 52-53, 55-57, 59-60, 62-64, 66-70, 72-86, drawn to a method of treating, preventing and ameliorating a hepatitis B virus infection, classified in class 424, subclass 227.1.
- II. Claims 87-96, drawn to to a method of treating, preventing and ameliorating a hepatitis C virus infection, classified in class 424, subclass 228.1.

The inventions are distinct, each from the other because of the following reasons:

4. Inventions I-II are directed to related processes of use for oligonucleotides containing the CpG motif. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design,

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mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have differing function or effect. The function of the invention of Group I is directed at providing treatment to subjects infected with hepatitis B virus; whereas, the function of the invention of Group II is directed at providing treatment for subjects infected with hepatitis C virus.

Additionally, HBV differs from HCV phenotypically and genotypically. Hence, a different field of search would be required for each of the listed inventions. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

5. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper. Addition, because of the distinctiveness of the virus infecting each of the particular subject group, a different field of search would be required for each of the listed inventions. Hence, a restriction between distinct inventions is necessary and proper.

6. Claims 50, 57, 64, 70, 77, 82, 87 and 92 are generic to the following disclosed patentably distinct species: a nucleic acid sequence 5'-AACGTT-3' and a nucleic acid sequence 5'-GACGTT-3'. The species are independent or distinct because the nucleic acid sequences are different from one another. In the instant, each are expected to have different biological properties, such as differing cytokine production profile.

Moreover, a different field of search would be required for each of the distinct sequences. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

7. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. **If claims are added after the election, applicant must indicate which are readable upon the elected species.** MPEP § 809.02(a).

8. Applicant is advised that the reply to this requirement to be complete must include (i) **an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143)** and (ii) **identification of the claims encompassing the elected invention.**

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of

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record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.


9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Emily Le 9/27/06  
Patent Examiner  
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